

Sean R. Kelly (skelly@saiber.com)
Katherine A. Escanlar (kescanlar@saiber.com)
SAIBER LLC
18 Columbia Turnpike
Suite 200
Florham Park, NJ 07932
(973) 645-4801

Of Counsel:

Richard J. Berman (richard.berman@arentfox.com)
Janine A. Carlan (janine.carlan@arentfox.com)
Aziz Burgy (aziz.burgy@arentfox.com)
Bradford C. Frese (bradford.frese@arentfox.com)
Ahmed Abdel-Rahman (ahmed.abdel-rahman@arentfox.com)
ARENT FOX LLP
1717 K Street NW
Washington, DC 20006-5344
(202) 857-6000

Attorneys for Defendant and Counterclaim Plaintiff
Par Pharmaceutical, Inc.

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

JAZZ PHARMACEUTICALS, INC.,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS, LLC,
PAR PHARMACEUTICAL, INC., SUN
PHARMACEUTICAL INDUSTRIES LTD.,
OHM LABORATORIES INC., and
RANBAXY INC.,

Defendants.

C.A. No. 2:15-cv-03217-ES-JAD

**DEFENDANT PAR PHARMACEUTICAL, INC.'S
ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS**

Defendant Par Pharmaceutical, Inc. (“Par” or “Defendant”) by and through its attorneys,
for its Answer to the Complaint of Plaintiff Jazz Pharmaceuticals, Inc. (“Jazz” or “Plaintiff”),
hereby declares as follows:

NATURE OF THE ACTION

1. Par admits that the Complaint purports to be an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, arising from Par's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Jazz's XYREM drug product prior to the expiration of United States Patent No. 8,952,062 (the "'062 patent" or the "patent-in-suit"). Par is without knowledge and information sufficient to form a belief as to whether Jazz owns the entire right, title, and interest in the patent asserted in this action, and thus denies all remaining allegations of Paragraph 1.

THE PARTIES

2. Par is without knowledge and information sufficient to form a belief as to the state of incorporation and principal place of business of defendant Jazz Pharmaceuticals ("Jazz"), and thus denies the allegations of Paragraph 2.

3. Par is without knowledge and information sufficient to form a belief as to the state of incorporation and principal place of business of defendant Amneal Pharmaceuticals, LLC ("Amneal"), and thus denies the allegations of Paragraph 3.

4. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 4, and thus denies the same.

5. Par admits that it is a corporation incorporated under the laws of the State of Delaware. Par denies any remaining allegations of Paragraph 5.

6. Par admits the allegations of Paragraph 6.

7. Par is without knowledge and information sufficient to form a belief as to the state of incorporation and principal place of business of defendant Sun Pharmaceutical Industries Ltd. ("Sun"), and thus denies the allegations of Paragraph 7.

8. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 8, and thus denies the same.

9. Par is without knowledge and information sufficient to form a belief as to the state of incorporation and principal place of business of defendant Ohm Laboratories Inc. (“Ohm”), and thus denies the allegations of Paragraph 9.

10. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 10, and thus denies the same.

11. Par is without knowledge and information sufficient to form a belief as to the state of incorporation and principal place of business of defendant Ranbaxy Inc. (“Ranbaxy”), and thus denies the allegations of Paragraph 11.

12. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 12, and thus denies the same.

13. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 13, and thus denies the same.

JURISDICTION AND VENUE

14. Paragraph 14 states a legal conclusion to which no response is required. To the extent a response is required, Par does not contest that this Court has jurisdiction over the subject matter of this action only.

15. Paragraph 15 states a legal conclusion to which no response is required. To the extent a response is required, Par states that they are without knowledge and information sufficient to admit or deny the allegations of this Paragraph and thus denies the same.

16. Paragraph 16 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that it conducts business in this judicial district. Par avers that it is a pharmaceutical company engaged in the manufacturing, marketing, and selling,

inter alia, of generic pharmaceutical products. Par admits specific personal jurisdiction in this judicial district for the limited purposes of this action only. Par admits that it is currently litigating, and has litigated in the past, cases in this District. Par admits that it has customers in the State of New Jersey. Par further admits that it is registered to conduct business in the State of New Jersey. Par denies any remaining allegations of Paragraph 16.

17. Paragraph 17 states a legal conclusion to which no response is required. To the extent a response is required, Par states that it is without knowledge and information sufficient to admit or deny the allegations of this Paragraph and thus denies the same.

18. Paragraph 18 states a legal conclusion to which no response is required. To the extent a response is required, Par states that it is without knowledge and information sufficient to admit or deny the allegations of this Paragraph and thus denies the same.

19. Paragraph 19 states a legal conclusion to which no response is required. To the extent a response is required, Par states that it is without knowledge and information sufficient to admit or deny the allegations of this Paragraph and thus denies the same.

20. Paragraph 20 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that Plaintiffs purport to base venue on 28 U.S.C. §§ 1391 and 1400(b). Par does not contest venue in this judicial district for the limited purpose of this action only. Par denies any remaining allegations of Paragraph 20.

THE PATENT-IN-SUIT

21. Par admits a document which appears to be the '062 patent is attached to the complaint as Exhibit A; that the '062 patent, on its face, is titled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy," and states the issue date is February 10, 2015. Par is without knowledge and information sufficient to form

a belief as to whether the '062 patent was assigned to Jazz. Par denies any remaining allegations of Paragraph 21.

THE XYREM DRUG PRODUCT

22. Paragraph 22 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that Jazz holds an approved New Drug Application (“NDA”) under Section 505(a) of the Federal Food Drug and Cosmetic Act (“FFDCA”), 21 U.S.C. § 355(a), for sodium oxybate oral solution (NDA No. 21-196), which it sells under the trade name XYREM. Par is without knowledge and information sufficient to form a belief as to whether Jazz owns the patent-in-suit. Par denies any remaining allegations of Paragraph 22.

23. Paragraph 23 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that the '062 patent is listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to XYREM. Par denies any remaining allegations of Paragraph 23.

ACTS GIVING RISE TO THIS SUIT

AMNEAL

24. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 24 and thus denies the same.

25. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 25 and thus denies the same.

26. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 26 and thus denies the same.

PAR

27. Par admits that it filed ANDA No. 205403 (“Par’s ANDA”) seeking approval to engage in the commercial use, manufacture, sale, and offer for sale of 500 mg/mL sodium

oxybate oral solution (“Par’s Proposed Product”) before the expiration of the patent-in-suit. Par denies any remaining allegations of Paragraph 27.

28. Paragraph 28 states a legal conclusion to which no response is required. To the extent a response is required, Par avers that it provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Par’s Paragraph IV Certification”), stating that the claims of the patent-in-suit are invalid, unenforceable, and/or will not be infringed by the product described in Par’s ANDA or the use of that product. Par denies any remaining allegations of Paragraph 28.

29. Paragraph 29 states a legal conclusion to which no response is required. To the extent a response is required, Par avers that Par sent Jazz a written notice of Par’s Paragraph IV Certification (“Par’s Notice Letter”) stating that the claims of the patent-in-suit are invalid, unenforceable, and will not be infringed by the product described in Par’s ANDA or the use of that product. Par denies any remaining allegations of Paragraph 29.

SUN

30. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 30 and thus denies the same.

31. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 31 and thus denies the same.

32. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 32 and thus denies the same.

COUNT I: AMNEAL’S INFRINGEMENT OF THE ’062 PATENT

33. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 32 of the Complaint. To the extent a response is required, Par hereby

incorporates by reference its responses to Paragraphs 1 through 32.

34. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 34 and thus denies the same.

35. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 35 and thus denies the same.

36. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 36 and thus denies the same.

37. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 37 and thus denies the same.

38. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 38 and thus denies the same.

39. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 39 and thus denies the same.

40. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 40 and thus denies the same.

41. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 41 and thus denies the same.

COUNT II: PAR'S INFRINGEMENT OF THE '062 PATENT

42. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 41 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 41.

43. Paragraph 43 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 43.

44. Paragraph 44 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 44.

45. Paragraph 45 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 45.

46. Paragraph 46 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 46.

47. Paragraph 47 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 47.

48. Par denies the allegations of Paragraph 48.

49. Par denies the allegations of Paragraph 49.

50. Paragraph 50 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 50.

COUNT III: SUN'S INFRINGEMENT OF THE '062 PATENT

51. No response is required to the general incorporation of the allegations set forth in Paragraphs 1 through 50 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 50.

52. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 52 and thus denies the same.

53. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 53 and thus denies the same.

54. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 54 and thus denies the same.

55. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 55 and thus denies the same.

56. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 56 and thus denies the same.

57. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 57 and thus denies the same.

58. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 58 and thus denies the same.

59. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 59 and thus denies the same.

ANSWER TO PLAINTIFF'S PRAYER FOR RELIEF

Par denies that Jazz is entitled to the relief it seeks in Paragraphs (A)–(K) or any relief at all for the allegations made in the Complaint.

AFFIRMATIVE DEFENSES

60. Par pleads the following defenses in response to Jazz's allegations, undertaking the burden of proof only as to those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated herein. Par reserves the right to allege additional defenses in the event that discovery or other analysis indicates that additional affirmative or other defenses are appropriate.

FIRST AFFIRMATIVE DEFENSE
(INVALIDITY OF U.S. PATENT NO. 8,952,062)

61. The claims of the '062 patent are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

SECOND AFFIRMATIVE DEFENSE
(NONINFRINGEMENT OF U.S. PATENT NO. 8,952,062)

62. The manufacture, use, sale, offer to sell or importation into the United States of Par's Proposed Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '062 patent, either literally or under the doctrine of equivalents.

THIRD AFFIRMATIVE DEFENSE
(FAILURE TO STATE A CLAIM)

63. Each purported claim for relief in the Complaint is barred for failure to state a claim upon which relief can be granted.

FOURTH AFFIRMATIVE DEFENSE
(PROSECUTION LACHES)

64. Jazz unexplainably and unreasonably delayed prosecuting the application that led to the issuance of the '062 patent.

65. Par has invested substantial resources in preparing and filing Par's ANDA and developing the 500 mg/ml oral sodium oxybate solution that is the subject of Par's ANDA.

66. Jazz's unexplained and unreasonable delay in prosecuting the application that led to the '062 patent has prejudiced Par.

67. The '062 patent is unenforceable due to the equitable defense of prosecution laches.

COUNTERCLAIMS

1. Counterclaim-Plaintiff, Par Pharmaceutical, Inc. ("Par"), asserts the following Counterclaims against Plaintiff/Counterclaim-Defendant Jazz Pharmaceuticals, Inc. ("Jazz") for declaratory judgment that U.S. Patent No. 8,952,062 (the "'062 patent" or the "patent-in-suit") is not infringed by the product described in Par's ANDA No. 205403 ("Par's Proposed Product"), and/or is invalid for violation of one or more provisions of Title 35 of the United States Code,

including 35 U.S.C. §§ 101, *et seq.*

THE PARTIES

2. Counterclaim-Plaintiff Par is a corporation organized under the laws of Delaware with a place of business and corporate headquarters at One Ram Ridge Road, Spring Valley, New York 10977.

3. On information and belief, and based upon Jazz's allegations, Counterclaim-Defendant/Plaintiff Jazz Pharmaceuticals, Inc. ("Jazz") is a Delaware corporation with its principal place of business at 3180 Porter Drive, Palo Alto, California 94304.

NATURE OF THE ACTION

4. These Counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Par seeks declaratory relief—a declaration that the patent-in-suit is not infringed by the sodium oxybate product described in Par's Abbreviated New Drug Application ("ANDA") No. 205403 and/or is invalid for failure to comply with one or more provisions of Title 35 of the United States Code, including 35 U.S.C. §§ 101, *et seq.*

5. As a consequence of Jazz's Complaint against Par, there is now an existing, continuing actual controversy between Jazz and Par regarding the alleged infringement and validity of the '062 patent.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of these Counterclaims pursuant to §§ 1331 and 1338(a) of Title 28 of the U.S. Code, as they involve claims arising out of the United States Patent Act, 35 U.S.C. §§ 1, *et seq.*

7. This Court may declare the rights and legal relations for the parties pursuant to §§ 2201 and 2202 of Title 28 of the U.S. Code and § 271(e)(5) of Title 35 of the United States Code

because Par's Counterclaims present an actual controversy within the Court's jurisdiction.

8. Venue for these Counterclaims is proper within this District in which Jazz's Complaint is pending.

BACKGROUND

9. The '062 patent, on its face, is titled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy" and states its date of issue as February 10, 2015, and is attached to this document as Exhibit A.

10. On information and belief, and based on Jazz's allegations, Jazz is the holder of New Drug Application ("NDA") No. 21-196 for sodium oxybate oral solution, sold in the United States as XYREM.

11. On information and belief, the FDA approved NDA No. 21-196 on July 17, 2002.

12. Par submitted ANDA No. 205403 to the FDA, requesting approval to engage in the commercial manufacture, use, importation, sale, and/or offer for sale in the United States of a 500 mg/mL sodium oxybate oral solution ("Par's Proposed Product") before the expiration of the '062 patent. On March 20, 2015, Par made an amendment to ANDA No. 205403 to provide supplementary certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that no valid or enforceable claim of the '062 patent would be infringed by the commercial manufacture, use, importation, sale, and/or offer for sale of Par's Proposed Product.

13. On March 20 2015, Par sent a letter to Jazz stating that Par's ANDA No. 205403 contained a Paragraph IV Certification regarding the '062 patent.

14. On May 7, 2015, Jazz filed its Complaint alleging infringement by Par of the patent-in-suit.

COUNT I: DECLARATION OF INVALIDITY OF THE '062 PATENT

15. Par incorporates Paragraphs 1-14 of its Counterclaims by reference.

16. The claims of the '062 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code including 35 U.S.C. §§ 101, *et seq.*, specifically including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112.

17. A definite and concrete, real and substantial, justiciable controversy exists between Par and Jazz concerning the validity of the '062 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

18. Par is entitled to a judicial declaration that the '062 patent is invalid.

COUNT II: DECLARATION OF NONINFRINGEMENT OF THE '062 PATENT

19. Par incorporates Paragraphs 1-18 of its Counterclaims by reference.

20. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's Proposed Product does not and will not literally infringe or infringe under the doctrine of equivalents, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '062 patent.

21. A definite and concrete, real and substantial, justiciable controversy exists between Par and Jazz concerning the alleged infringement by Par's Proposed Product of the '062 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

22. Par is entitled to a judicial declaration that each valid and enforceable claim of the '062 patent is not infringed.

COUNT III: EXCEPTIONAL CASE

23. Par incorporates Paragraphs 1-22 of its Counterclaims by reference.

24. This case is an exceptional case under 35 U.S.C. § 285 and Par is entitled to receive its reasonable costs and attorney's fees incurred in connection with this action.

PAR'S PRAYER FOR RELIEF

WHEREFORE, Par requests the following relief:

- a) Dismissing the Complaint with prejudice and denying each request for relief made by Jazz;
- b) Declaring all claims of the '062 patent invalid;
- c) Declaring all claims of the '062 patent not infringed by the making, use, sale, offer for sale, marketing, or importation into the United States of Par's Proposed Product;
- d) Awarding Par its reasonable costs and attorney's fees incurred in connection with this action pursuant to 35 U.S.C. § 285; and
- e) Awarding Par such other and further relief as the Court deems just and proper.

June 12, 2015

OF COUNSEL:

Richard J. Berman
Janine A. Carlan
Aziz Burgy
Bradford C. Frese
Ahmed Abdel-Rahman
ARENT FOX LLP
1717 K Street, NW
Washington, DC 20006-5344
(202) 857-6000
richard.berman@arentfox.com
janine.carlan@arentfox.com
aziz.burgy@arentfox.com
bradford.frese@arentfox.com
ahmed.abdel-rahman@arentfox.com

Respectfully submitted,

s/ Sean R. Kelly
Sean R. Kelly
Katherine A. Escanlar
SAIBER LLC
18 Columbia Turnpike
Suite 200
Florham Park, NJ 07932
(973) 622-3333
skelly@saiber.com
kescanlar@saiber.com

*Counsel for Defendant and
Counterclaim-Plaintiff Par
Pharmaceutical, Inc.*

LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Par hereby certifies that this matter is related to the *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals LLC et al.*, Civil Action No. 13-00391 (ES)(JAD) and *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 15-03684 (ES)(JAD) matters pending before this Court. The undersigned counsel for Par further certifies that this matter is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding.

Dated: June 12, 2015

s/ Sean R. Kelly
Sean R. Kelly

LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Par hereby certifies that Par seeks declaratory relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: June 12, 2015

s/ Sean R. Kelly
Sean R. Kelly